

REMARKS

Applicants' counsel expresses his appreciation for the courteous interview granted by the Examiner on December 2, 2008. During the course of the interview, the claims and prior art were discussed. The Examiner made some suggestions in order to improve the chances of allowance.

Applicants had hoped to file a supplemental response soon after the interview but were unable to complete the response prior to the issuance of the current outstanding Office Action.

One of the suggestions made by the Examiner was to amend the independent claim to include the specific wavelength ranges being used for treatment.

In response to this suggestion, applicants have amended the sole independent claim to specify that the radiation from the lamp is filtered "to produce a spectrum having a wavelength band principally between 1050nm and 1850nm." As described in the specification at page 10, line 25, a filter 422 is used to block radiation below 1050nm. Page 11, line 18 as well as Figures 5, 6 and 7 provide support for the 1850nm upper limit. In this regard, the Examiner should note that curve 502 of Figure 5 shows how the intensity of the light from the source is dropping rapidly above 1850nm. Conversely, Figure 6 shows how the absorption in water of radiation above about 1800nm is rapidly rising. As noted in the specification, in the preferred embodiment, the filament lamp is surrounded by a water jacket which provides the additional filtering referred to on page 11. Accordingly, the upper limit of 1850nm is also supported by the specification. (See also the Davenport Declaration on the selection of the appropriate wavelength and filtering.)

The Examiner also suggested that it would be worthwhile to submit a declaration helping to support the patentability of the claims. Accordingly, submitted herewith is a declaration of Scott Davenport, one of the engineers that worked on developing the Titan product. The Davenport declaration describes some of the historical development of prior products at Cutera as a background for the subject invention. The Davenport declaration also describes the genesis of the development of Cutera's Titan product, a filament lamp based system sold commercially for skin tightening. The Davenport declaration also describes the unique benefits of using broadband infrared radiation in the range of 1050nm to 1850nm, coupled with long pulses and cooling to create the desired tissue effect. The Davenport declaration also discusses the sales of the Titan product.

In the Office Action, the Examiner rejected the previous claims as being unpatentable over Altshuler (2004/0093042), in view of Altshuler (2002/0173780) in further view of Anderson (6,120,497).

It was the Examiner's position that these references demonstrate a "thorough and sophisticated understanding of the interaction between skin tissue and the wavelengths to which it is exposed." There is no doubt that these references disclose a fair amount of general knowledge about light and tissue interaction. The problem arises when one attempts to actually produce a product or develop a treatment modality which actually works. Altshuler '3042 in particular is a document which discloses a wide ranging parameter space describing all types of light sources for all types of procedures. However, the devil is in the details. As described in the Davenport declaration, finding just the right mix of parameters is not a trivial exercise and requires much more than routine experimentation.

More importantly, the Examiner's rejection does not focus deeply enough on what Altshuler actually teaches in the '3042 application. As will be discussed in greater detail below, Altshuler actually teaches away from the claimed parameters. While it is true that patentability can be shown by unexpected results, a prima facie case of obviousness can also be rebutted when it appears that the prior art teaches away from the claimed parameters (see MPEP 2144.05 III).

In order to understand the teachings of Altshuler '3042, applicants will need to drill down to discuss his various examples in more detail. When those details are studied, it will become apparent that Altshuler '3042 teaches something quite different from the invention that is being claimed and moreover, the secondary references will fail to supply any missing teachings.

One important difference between Altshuler'3042 and independent claim 15 is seen very early on in the Detailed Description at paragraph 30. This is the primary paragraph in the entire specification that deals most directly with wrinkle removal or skin tightening. Here, Altshuler teaches that the underlying tissue should be heated to a temperature between 37.5 and 45 degrees. In contrast, independent claim 15 herein requires that the tissue be heated to at least 50 degrees and preferably at least 60 degrees (claim 33). Altshuler teaches away from applicants' invention.

In discussing fat or cellulite reduction, Altshuler again teaches that the temperature should be elevated but remain below the damage threshold of 43 to 48 degrees (see paragraph 36).

The specification concludes with three “examples.” The first example, beginning at paragraph 67, is merely a theoretical calculation. The second example is again theoretical - “a prophetic example.” In the Office Action, the Examiner pointed specifically to paragraph 93 of the prophetic example to demonstrate that Altshuler teaches applicants’ invention. However, paragraph 93 contains no teaching of the desired tissue temperature.

Paragraph 93 does include some typical all inclusive range comments related to wavelength and treatment time. For wavelength, he first suggests filtering more than 50% of light having wavelengths less than 800nm and greater than 1800nm, preferably 900n to 1400nm and most preferably 1100nm to 1250nm. What exactly do those multiple ranges teach? First, they teach that it more preferable to have a narrower range than a broad range. It does not specifically teach applicants claimed range of 1150nm to 1850nm. More importantly, it teaches that it would acceptable to filter only “more than 50%” outside the specified end points. Permitting anywhere close to 50% of the light below 800nm to reach the tissue would not lead to acceptable performance and teaches away from applicants’ invention.

Regarding treatment time, paragraph 93 suggests 2 seconds for a depth of 1mm and 7300 seconds (**2 hours!**) for depth of 50mm. Applicants’ method of claim 15 is seeking to treat a region from 1 to 5 mm millimeters for a time period of 1.2 to 5 seconds. Table 1 of Altshuler teaches that for 2 to 5mm, the treatment time should be 10 to 40 seconds. So Altshuler really teaches that for 1 to 5mm, the time period should be 1 to 40 seconds where the upper limit is 8 times longer than in applicants’ claim.

Altshuler’s third example (starting at paragraph 96) uses a halogen lamp with an 800nm cut off filter and water layer. In a first test, stomach fat was treated for 300 seconds. A temperature of only 45 degrees was reached at a depth of 8mm. In a second test, a piece of pig skin was treated, again for 300 seconds. Here a peak temperature of 53 degrees was reached in the excised tissue at a depth of 14mm. Presumably the temperature exceeded 50 degrees only because the tissue was not part of a living animal. Regardless, the remaining treatment parameters were wholly outside applicants’ claimed ranges and teach away from applicants’ invention.

Altshuler ‘3780 was cited for its alleged teaching of cooling before, during and after treatment. However, Altshuler ‘3780 has no teachings which overcome the shortcomings of Altshuler ‘3042 with respect to claim 15.

In the Office Action, the Examiner relies upon Anderson for its teaching of heating collagen to a temperature about 60 to 70 degrees. There are a few problems with this argument. First, the primary teaching of Altshuler '3042 is to keep the temperature rise in the tissue below 50 degrees. This is particular true in paragraph 30, the one place where Altshuler is focused on talking about collagen treatment for wrinkle removal. Here, Altshuler specifically teaches that the temperature should be between 37.5 degrees and 45 degrees. If is simply not a proper rejection to state that one skilled in the art would ignore the express teachings of Altshuler on collagen treatment and wrinkle removal and substitute the teachings from a different reference. It is well settled that a proposed combination cannot produce a result that goes directly against the teachings of the primary reference.

Beyond that problem, and as discussed above, Altshuler '3042 fails to teach either applicants' broadband infrared wavelength limitation or applicants' treatment time. Anderson of course fails to teach these limitations as well since he teaches using a laser for such treatment. In Anderson's embodiment, the radiation is narrowband and delivered in short pulses. Thus, Anderson fails to overcome the deficiencies of the two Altshuler references in rendering obvious applicants' claims.

The Examiner is reminded that the parameters of the method of claim 15 actually do produce a skin tightening effect as demonstrated by the articles submitted in response to the last Office Action. Further, over 3500 handpieces carrying the claimed technology have been sold at a price of at least \$45,000 apiece.

In reviewing the previous amendment, it was noted that the text did not specifically identify the references attached as Exhibit A to D. For completeness, the previously submitted references are listed at the end of this document.

In the previous telephone conference, the Examiner noted that the articles referred to the wavelength range in rounded numbers, specifically 1100nm to 1800nm. These rounded numbers are used by Cutera for its marketing materials supplied to physicians. As noted in the Davenport Declaration, the wavelength output of the Titan handpiece is closer to 1050 to 1850 as set forth in claim 15.

In the Office Action, the Examiner cited Fullmer (5,885,274) against claim 40 for its teaching of a filament lamp. Fullmer fails to overcome the deficiencies of the primary references in rendering obvious the subject matter of amended independent claim 15.

In the Office Action, the Examiner cited the Vaynberg (2005/0107850) against claim 41 for its teaching of controlling the light source. Vaynberg fails to overcome the deficiencies of the primary references in rendering obvious the subject matter of amended independent claim 15.

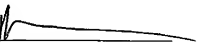
Based on the above, it is respectfully submitted that independent claim 15 defines patentable subject matter and allowance thereof, along with the claims depending therefrom is respectfully solicited.

List of Previously submitted references:

- David J. Goldberg, et al., "Treatment of skin laxity of the lower face and neck in older individuals with a broad-spectrum infrared light device," *Journal of Cosmetic and Laser Therapy*, Vol. 9 (2007), pp. 35-40.
- Javier Ruiz-Esparza, "Near Painless, Nonablative, Immediate Skin Contraction Induced by Low-Fluence Irradiation with New Infrared Device: A Report of 25 Patients," *Dermatol. Surg.*, Vol. 32 (2006), pp. 601-610.
- Sze-Hon Chua et al., "Nonablative Infrared Skin Tightening in Type IV and V Asian Skin: A Prospective Clinical Study," *Dermatol. Surg.*, Vol. 33 (2007), pp. 146-151.
- Amy Forman Taub et al., "Multicenter Clinical Perspectives on a Broadband Infrared Light Device for Skin Tightening," *Journal of Drugs in Dermatology*, September 1, 2006, pp. 771-778.

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